

## California's New Law Limiting Mercury in Vaccines: Frequently Asked Questions

### Letter and impact of the law

#### **Q. What does the mercury law say?**

A. As of July 1, 2006 California law prohibits administering vaccines whose mercury content exceeds the legal limit to:

- Women who are "knowingly pregnant" or
- Children under the age of 3 years.

Legal limit: Vaccines given to pregnant women or to children under the age of 3 years in California may not exceed:

- 1.0 microgram of mercury per 0.5 milliliters of influenza vaccine
- 0.5 micrograms of mercury per 0.5 milliliters of all other vaccines
- Note: Most vaccines are administered in 0.5 milliliter doses, but the dose of influenza vaccine for children age six months to 23 months is 0.25 milliliters.

Exemptions: The law allows California's Governor and Secretary of Health and Human Services to permit providers to administer vaccines that exceed the mercury limit if there an epidemic, vaccine shortage, or other public health emergency.

Penalties: Penalties for violation are not specified in the law

Text of the law is available at:

[www.leginfo.ca.gov/pub/03-04/bill/asm/ab\\_2901-2950/ab\\_2943\\_bill\\_20040928\\_chaptered.html](http://www.leginfo.ca.gov/pub/03-04/bill/asm/ab_2901-2950/ab_2943_bill_20040928_chaptered.html).  
(California Health and Safety Code 124172: Chapter 837, Statutes of 2004, AB 2943, Pavley)

#### **Q. Will the mercury law affect my administration of influenza vaccine?**

A. Possibly. Formulations of influenza vaccine vary as to whether they

- meet the legal limit for mercury content; for example, multi-dose vials of influenza vaccine exceed the limit
- are licensed for use in pregnant women and children under 3 years of age

Please review the list of influenza vaccines at [www.getimmunizedca.org](http://www.getimmunizedca.org) in order to provide your patients with vaccine formulations that comply with the new law.

#### **Q. Will the mercury law affect my administration of routine vaccines besides influenza vaccine?**

A. No. All vaccines other than influenza vaccine commonly given to pregnant women and children under 3 years of age meet the legal limit for mercury content

#### **Q. Which multi-dose vaccines besides influenza vaccine are restricted by the new law?**

A. Certain multi-dose formulations of DT, TT, Td and meningococcal polysaccharide vaccine exceed the mercury limit for pregnant women and children under 3 years of age. Alternatives to these formulations are readily available. For more information on these vaccines and their alternatives, please refer to the summary chart *Vaccines (other than influenza vaccine) in a Multi-dose Vial Formulation that Exceed the California Legal Limit for Mercury Content—July 2006* at [www.getimmunizedca.org](http://www.getimmunizedca.org).

## **Mercury and vaccine safety**

### **Q. Why has mercury been used in vaccines?**

A. The vaccine preservative thimerosal contains ethylmercury. Thimerosal has been used in vaccines since the 1930s to prevent bacterial contamination of vaccines, especially those stored in multi-dose vials. In recent years advances in vaccine manufacturing have enabled thimerosal to be phased out of most vaccine production. By the time the mercury law was enacted, the only routinely-used childhood vaccine that did not meet the law's limits was the multi-dose vial formulation of influenza vaccine.

### **Q. Why was this law passed?**

A. Thimerosal has been hypothesized to be a cause of childhood autism. This hypothesis is not supported by the results of extensive study. However, proponents of the law remain concerned about exposure to thimerosal.

### **Q. How can I reassure my patients about vaccine safety?**

A. When Governor Schwarzenegger signed the law, he said, *"While I take this action in an abundance of caution, I want to encourage parents to get their children vaccinated. There are significant risks associated with the failure to vaccinate children which far outweigh any theoretical risk associated with thimerosal."*

According to the Centers for Disease Control and Prevention (CDC) *there is no conclusive evidence that any vaccine or vaccine additive increases the risk of developing autism or any other behavior disorder. Rather, evidence is accumulating of lack of any harm resulting from exposure to vaccine containing thimerosal as a preservative.*

An April 3, 2006 letter to Congress stated that *"...there is no documented scientific evidence that ethylmercury in the form of thimerosal in the doses administered in vaccines causes any risk to health."* The letter was signed by representatives of the American Academy of Pediatrics, American Academy of Family Physicians, American College of Preventive Medicine, American Medical Directors Association, American Pharmacists Association, Pediatric Infectious Diseases Society, and Society for Adolescent Medicine.

The following are additional sources of information about mercury and vaccines.

- ❖ The CDC provides information on vaccine safety for consumers and health care providers at: [www.cdc.gov/nip/vacsafe/concerns/thimerosal/default.htm](http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/default.htm)
- ❖ Food and Drug Administration (FDA) background on thimerosal can be found at: [www.fda.gov/cber/vaccine/thimerosal.htm](http://www.fda.gov/cber/vaccine/thimerosal.htm).
- ❖ The American Academy of Pediatrics has information about vaccines and autism at: [http://www.cispimmunize.org/pro/pro\\_main.html?http&&www.cispimmunize.org/pro/safety.html](http://www.cispimmunize.org/pro/pro_main.html?http&&www.cispimmunize.org/pro/safety.html)
- ❖ The Children's Hospital of Philadelphia's website contains a comprehensive summary of studies that indicates that "evidence showing that, while some things do cause autism, mercury in vaccines isn't one of them." For more information go to: [www.chop.edu/consumer/jsp/division/generic.jsp?id=75751](http://www.chop.edu/consumer/jsp/division/generic.jsp?id=75751)
- ❖ Immunization Safety Review: "Vaccines and Autism," a report by the Institute of Medicine, May 2004 visit: [www.iom.edu/CMS/3793/4705/20155.aspx](http://www.iom.edu/CMS/3793/4705/20155.aspx)

## Influenza Vaccines and California's Mercury Law—July 2006

**A) The following influenza vaccine meets the new law's mercury limit and is currently licensed for use in children younger than 3 years old:**

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Packaged as</u>
Sanofi Pasteur Inc.	Fluzone® no preservative pediatric dose (children 6-35 months of age)	prefilled 0.25 mL unit dose syringes

**B) The following influenza vaccines meet the new law's mercury limit and may be given to pregnant women:**

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Packaged as</u>
Chiron Corporation	Fluvirin® preservative-free	prefilled 0.5 mL syringes
GlaxoSmithKline	Fluarix®	prefilled 0.5 mL unit dose syringes
Sanofi Pasteur Inc.	Fluzone® no preservative	0.5 mL unit dose vial
Sanofi Pasteur Inc.	Fluzone® no preservative	prefilled 0.5 mL unit dose syringes

**C) The following influenza vaccines meet the new law's mercury limit but are not currently licensed for use in children under 3 years old:**

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Packaged as</u>
GlaxoSmithKline	Fluarix®	prefilled 0.5 mL unit dose syringes
MedImmune Inc.	FluMist®	prefilled 0.5 mL unit dose nasal sprayer
<i>FluMist® is also <u>not</u> currently licensed for use in pregnant women</i>		

**D) The following influenza vaccines exceed the new law's mercury limit:**

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Packaged as</u>
Chiron Corporation	Fluvirin®	5 mL multi-dose vial
Sanofi Pasteur Inc.	Fluzone®	5 mL multi-dose vial
[GlaxoSmithKline	Fluviral®	5 mL multi-dose vial
GlaxoSmithKline	Fluviral®	prefilled 0.5 mL unit dose syringes
<i>Fluviral® is currently under FDA review for use in the U.S. in the 2006-2007 season.]</i>		

**Vaccines (other than influenza vaccine) in a Multi-dose Vial Formulation  
that Exceed the California Legal Limit for Mercury Content—July 2006**

<b>Abbreviation</b>	<b>DT</b>	<b>TT</b>	<b>Td</b>	<b>MPSV4</b>
<b>Full name</b>	Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use)	Tetanus Toxoid Adsorbed USP (5 Lf/dose)  Tetanus Toxoid For Booster Use Only (4 Lf/dose)	Tetanus and Diphtheria Toxoids Adsorbed For Adult Use	Meningococcal Polysaccharide Vaccine Groups A,C,Y and W-135 Combined (Trade name: <i>Menomune®-A/C/Y/W-135</i> )
<b>Manufacturer</b>	Sanofi Pasteur	Sanofi Pasteur	Massachusetts Biologic Laboratories	Sanofi Pasteur
<b>Formulation</b>	5 mL 10-dose vial	5 mL 10-dose vial	5 mL 10-dose vial	5 mL 10-dose vial
<b>Use in infants and toddlers?</b>	Infrequent	No; labeled for $\geq 7$ years	No; labeled for $\geq 7$ years	Rare; labeled for $\geq 2$ years
<b>Use in pregnant women?</b>	No; labeled up to 7 <sup>th</sup> birthday	Rare	Infrequent	Rare
<b>Alternatives which meet California law?</b>	0.5 ml single-dose vial of DT from same manufacturer	0.5 ml single-dose vial of TT from same manufacturer	0.5 ml single-dose vial of Td from Sanofi Pasteur	0.5 ml single-dose vial of MPSV4 from same manufacturer
<b>Additional comments</b>	Most infants and children should receive DTaP vaccine instead of DT.	Pregnant women should receive Td vaccine instead of TT.	This formulation of Td is seldom available outside of Massachusetts.	Pregnant women at high risk of meningococcal disease may receive meningococcal conjugate vaccine (MCV4) when available instead of MPSV4. As of June, 2006, FDA is reviewing a request for MCV4 to be re-labeled for use at $\geq 2$ years of age.